

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **27 OCTOBER 2004 (27.10.2004)**

Applicant's or agent's file reference
PCTA9407-2

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/KR2004/001819

International filing date (day/month/year)
21 JULY 2004 (21.07.2004)

Priority date(day/month/year)
30 JANUARY 2004 (30.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC7 C12N 15/54, C12N 15/04, C12N 9/10

Applicant

Korea Research Institute of Bioscience and Biotechnology et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



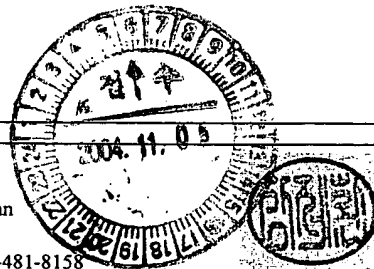
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**WRITTEN OPINION OF THE
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International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☒ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☒ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 11

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11
are so unclear that no meaningful opinion could be formed (*specify*):

Claims 11 relates to glycoprotein produced by method according to Claims 8 or 9. However, the glycosylation pattern of glycoprotein claimed is not clear to perform meaningful search.

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard.

the computer readable form ☐ has not been furnished

☐ does not comply with the standard.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------|-----|
| Novelty (N) | Claims | 1-10 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-10 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 1-10 | YES |
| | Claims | | NO |

2. Citations and explanations :

The following documents are cited in the International Search Report;

- D1 : Proc. Nat'l Acad. Sci., Vol.100, April 2003, pages 5022-5027, B. K. Choi. et al.
D2 : Glybiology, Vol.5, 1995, pages 671-681, M. G. Verostek et al.
D3 : J. Biological Chemistry, Vol.273, October 1998, pages 26298-26304, Y. Chiba et al.
D4 : J. Biological Chemistry, Vol.268, December 1993, pages 26338-26345, Y. Nakanishi-Shindo et al.
D5 : US 2004/0137134 A (T. U. Gerngross) 26 September 2002
D6 : KR 2004/0004089 A (KRIBB) 13 January 2004

D1 to D5 disclose α 1,6-mannosyltransferases from various yeast strains. In addition, the documents also disclose that α 1,6-mannosyltransferase can be used for producing glycoengineered protein, especially characterized in having a structure of Man5GlcNAc2 and Man8GlcNAc2.

D5 and D6 disclose a method for producing glycoproteins having a similar glycosylation pattern to the one produced in human by introducing a gene encoding enzyme involved in glycosylation including α 1,6-mannosyltransferase.

However, the documents set forth above do not provide any amino acid or nucleotide sequence with significant homology to sequences provided in this invention.

Therefore, claims 1 to 10 are novel and involve an inventive step.